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COOPERATIVE AGREEMENT DAMD17-96-2-6026

TITLE: Needs Assessment for Pregnancy and Sexually Transmitted Disease Prevention Among Military Women

PRINCIPAL INVESTIGATOR: Judith A. McDivitt, Ph.D.

CONTRACTING ORGANIZATION: Tulane University Medical Center
New Orleans, Louisiana 70112

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PREPARED FOR: Commander
U.S. Army Medical Research and Materiel Command
Fort Detrick, Frederick, Maryland 21702-5012

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The purpose of this research was to understand the needs of deployed and deployable military women, with respect to pregnancy and sexually transmitted disease prevention. The studies proposed to examine both supply-side (health service providers) and demand-side (women's compliance) issues using a combination of qualitative and quantitative research methods. The research was to take place at eight sites in the southern U.S., Honduras, and Panama and to include samples of Air Force, Army, and Navy women in the Military Reserve and National Guard, on Active Duty in the Continental United States, and those deployed overseas. The needs assessment consisted of two phases -- 1) a facility analysis and an ethnographic study, and 2) a large-sample survey. The first year of the project was spent submitting the Phase 1 protocol for the necessary approvals, making requested revisions to the protocol and the sample of military bases, and resubmitting the protocol. The Department of the Army has asked to negotiate a termination of the contract because of the investigators' inability to obtain these approvals. These negotiations are currently in progress and all activities in the scope of work have been stopped.

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FOREWORD

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____ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

NA For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

____ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

____ In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Judith A. Wood 10/29/97

PI - Signature Date

## TABLE OF CONTENTS

## INTRODUCTION

The purpose of this study was to understand the special needs of deployed and deployable women, with respect to pregnancy and sexually trasmitted disease (STD) prevention. This study proposed to examine both supply-side (health service providers) and demand-side (women's compliance) issues which put military women at risk of unintended pregnancy and sexually transmitted diseases (STDs). The information gathered in this investigation was expected to be valuable to health policy-makers, health educators, and health care providers in the military, as they continue to adapt military health care services in response to the growing number of women in military service.

The specific technical objectives of the study were 1) to assess the quality and accessibility of contraceptive and STD services at U.S. military bases, and 2) to identify the psychosocial and situational factors which contribute to the risk of pregnancy and STDs among deployed and deployable women through a combination of qualitative and quantitative research methods.

Three different circumstances of enlisted women were considered -- 1) Military Reserve and National Guard, 2) Active Duty in Continental United States (CONUS), and 3) Deployed overseas. In addition, because conditions may differ across services, the sample included women in the Air Force, Army, and Navy. The original sites included:

Fort Polk, Leesville, Louisiana
Barksdale Air Force Base, Shreveport, Louisiana
Belle Chase Naval Air Station, Belle Chasse, Louisiana
Louisiana Army National Guard: Camp Beauregard, Pineville, Louisiana and Jackson Barracks, New Orleans, Louisiana
Keesler Air Force Base, Biloxi, Mississippi
Soto Cano Air Force Base, Honduras
Howard Air Force Base and Gorgas Army Hospital, Panama

## BODY

Two major activities were specified in the scope of work for the first year of the project -- the facility analysis and the ethnographic research (see Appendix A). The primary tasks to be completed included: pretesting and finalizing instruments, selecting the samples, and data collection, entry, analysis, and reporting.

Pretesting of the facility analysis instruments and preliminary sample identification and selection for both studies were conducted. The other activities listed in the scope of work were not started because of the researchers' inability to obtain the necessary approvals to

conduct the research on the bases in the sample. The primary activities during the first year of this project revolved around the process of applying to and responding to the concerns of multiple Institutional Review Boards (see Appendix B). By the beginning of June, nine months after the start of the project, the research group had obtained approval to start work at one of the seven sites in the sample. In July, the Department of the Army requested that the researchers negotiate a termination of the cooperative agreement because of the lack of success in obtaining the necessary approvals (see Appendix C). Negotiations are in progress and all work on the project has stopped (see Appendix D).

A description of the study methodologies proposed for the Year 1 studies is included in Appendix E.

## APPENDIX A -- STATEMENT OF WORK

**Technical Objective 1:** Facility analysis of pregnancy- and STD-prevention services for military women.

| | | |
|---|---|---|
| Task 1: | Months 1-2: | Pretesting, finalization, and printing of health care provider interview schedule. Development of facility inventory checklist. |
| Task 2: | Months 1-3: | Recruit and train interviewers and inventory takers. |
| Task 3: | Months 4-6: | Field facility analysis at seven sites. Interviews with health care providers, visit and inventory military health facilities. |
| Task 4: | Months 5-7: | Data entry/transcribe interviews. |
| Task 5: | Months 8-11: | Data analysis. |
| Task 6: | Months 12-13: | Write up results. |

**Technical Objective 2:** Ethnographic research with deployable and deployed military women.

| | | |
|---|---|---|
| Task 1: | Months 1-2: | Recruit and train interviewers for in-depth interviews. |
| Task 2: | Month 3-4: | Conduct interviews and begin analysis. |
| Task 3: | Month 5: | Finalize Rapid Assessment guides. Train interviewers in rapid assessment techniques. |
| Task 4: analysis. | Months 6-8: | Conduct Rapid Assessment. Transcribe notes and begin |
| Task 5: necessary. | Months 8-10: | Continue analysis, and collect more information as |
| Task 6: | Months 11-12: | Write up results. |

**Technical Objective 3:** Survey of active duty and reserve women.

| | | |
|---|---|---|
| Task 1: | Months 13-15: | Development, pretesting, and printing of interview schedule. Finalization of sampling frame and selection of sample. |
| Task 2: | Months 16-18: | Field survey and enter data. |
| Task 3: | Months 19-22: | Analyze data. |
| Task 4: | Months 23-24: | Write up results and final report. |

## APPENDIX B -- CHRONOLOGY OF ACTIVITIES

### PRE FUNDING ACTIVITIES

- **May 6, 1996** the investigators received notice that their proposal had been funded.

- **July 16**, the investigators received a memo from Catherine Smith (Human Review Specialist) at the Human Use Review and Regulatory Affairs Division at Ft. Detrick with suggested changes to the protocol and consent form and informing them that, once the new protocol had been approved by her office, it would also be necessary to get Institutional Review Board (IRB) approval from each participating site and get approval of the survey from the Army Personnel Survey Office.

- The investigators made the requested changes and resubmitted the protocol to the Tulane Medical Center (TMC) Institutional Review Board. This IRB had serious concerns about wording in the consent form that is counter to TMC policy (the paragraph about TMC responsibility for treatment for injury or illness arising from participation in the study). Only after receiving a special dispensation from the TMC Chancellor, did the IRB approved the protocol on **September 12.**

- The investigators sent the revised protocol and consent forms to Ft. Detrick and received an email on **September 18** confirming that the changes looked fine and that they should start the on site approval process, which they did.

### POST FUNDING ACTIVITIES

- The project was funded **September 26** and the investigators started working with their counterparts at each site to start the IRB approval process. The sites and activities are as follows:

- **Army** (original sites included Fort Polk, Camp Beauregard, Gorgas Army Hospital, and Soto Cano)

- **Fort Polk**

  In **early October**, Judith McDivitt sent a copy of the methodology section of the full protocol (phases 1 and 2) to Major Steven Klamerus, the counterpart at Fort Polk.

Major Klamerus said he would send the protocol through the proper channels at Fort Polk and then to the review committee at Brooke Army Medical Center (BAMC). The investigators understood that he needed only the methodology section and consent forms at this time and did not send the entire document.

In **early January**, Judith McDivitt faxed Major Klamerus to check on progress, and on **January 15** she received an email message from him that the Fort Polk IRB had approved the study on December 31, that it was on the agenda for the February review meetings at BAMC, and that he did not expect any problems getting approval.

**January 16**, Major Klamerus called to say that BAMC had some questions about missing pieces of the protocol and faxed a memo he had received from Helen Smith, protocol coordinator at BAMC. This memo detailed the basic requirements for protocol submission, including a summary sheet, application page, and impact statement.

On **January 17**, Dr. Klamerus received another fax asking for CV's for the principal investigators, the memo about the change in principal investigators, several requested changes to the consent forms, and a request that the consent forms be in a larger type. After receiving this fax, Judith McDivitt called Helen Smith to make sure she had a complete list of what the review board needed. In talking to Ms. Smith, she discovered that BAMC required a copy of the full protocol, not just the methodology section, instruments and consent forms that had been submitted at other bases. Dr. McDivitt also discovered that Major Klamerus had sent the full protocol, rather than just the protocol for phase 1. She made the requested changes to the consent forms and faxed them to Ms. Smith to review on **January 17.**

On **January 21**, Judith McDivitt compiled all the materials requested by Ms. Smith and attached them to a copy of the complete protocol for phase 1 of the study. She then sent the full application to BAMC by Federal Express. As far as Dr. McDivitt could tell, she submitted all the documents required. It is important to note that January 18 and 19 were a weekend, and January 20 was Martin Luther King Day, a holiday during which the Tulane School of Public Health building is closed. Also at this time, the group's contact at BAMC, Helen Smith, had a family emergency or illness and was out of the office for part of this time. This may explain why, as Dr. McDivitt understands it, the members of the review board did not get the new packet of materials until just before their meeting.

On **February 4**, Judith McDivitt received a phone message from Patricia Modrow, her primary contact at Ft. Detrick, asking why the protocol was being reviewed by the IRB at BAMC and asking her to call Marilyn Sharp, one of her colleagues. Ms. Sharp informed Dr. McDivitt that BAMC had major problems with the protocol and suggested that she call Lt. Col. Longfield, the head of the review committee at BAMC.

Lt. Col. Longfield informed Dr. McDivitt that the study had been rejected by the clinical investigation committee.

She faxed a copy of the committee's concerns on **February 19**. Major problems included the wording and referencing in the background section, confusion about hypotheses, concern about the generalizability of the sample and small size of some of the bases chosen, exclusion of officers from the study, and questions about the ethnographic methodology.

On **February 20**, the Tulane research group met to discuss this memo. Understandably, the members were distressed and confused. This study already had been approved by the initial peer reviewers, by the Tulane IRB (despite their objections), and by the Human Use Review and Regulatory Affairs Division at Ft. Detrick. In addition, the investigators did not want to lose the work they had already done to identify sites and develop collaborative relationships with individuals at these sites.

On **February 26,** Judith McDivitt called Lt. Col. Longfield to discuss whether it would be possible to revise the protocol in response to BAMC's concerns and resubmit it. She agreed that the committee would consider a new proposal and made some suggestions about possible new sites.

Dr. McDivitt then called Patricia Modrow and Danny Laspe, Contract Specialist at Ft. Detrick, to consult with them about resubmitting the protocol and to ask if changing the sites and sample would be a problem from their perspective. They agreed to the changes as long as the investigators stayed within the original budget and submitted a new scope of work and budget to reflect any changes made (this has not been done yet because the investigators still are not certain where they will be working).

In the meantime, Maj. Klamerus was reassigned to another state, so the investigators changed the point of contact at Fort Polk to Lt. Col. Briles. The investigators went through the memo from BAMC and addressed each item: doing a more thorough literature search, rewriting text, and checking our references in the background section; revising the purpose/hypothesis and technical objectives sections to make them more understandable; eliminating the two foreign sites (Soto Cano and Howard) and replacing them with Fort Hood and Pensacola Naval Air Station; including officers in the study; and giving more explanation in the description of the ethnographic studies. The instruments and consent forms were not changed.

This protocol was Federal Expressed to BAMC on **March 26**.

On **April 11**, Judith McDivitt telephoned Lt. Col. Longfield (BAMC) who noted the improvements in the protocol, but said it had been rejected again, this time primarily

due to concerns with the methodology for the rapid ethnographic assessment and whether "don't ask, don't tell" would preclude women from being able to answer any questions about sexual behavior. She suggested that the investigators limit their research to the Air Force and the Navy. Although Dr. McDivitt has requested a written copy of the committee's comments, she has not yet received this.

- **Army National Guard and Soto Cano**

  Because these sites are under the jurisdiction of BAMC, the investigators have had to eliminate them from the study.

- **New sites**

  On **April 16** Judith McDivitt sent a memo to Dr. Modrow (copied to Ms. Smith and Mr. Laspe at Ft. Detrick) proposing that the study be carried our only at Air Force and Navy bases (as advised by Lt. Col. Longfield) and suggesting seven possible sites. Dr. Modrow requested that the investigators try to find some Army sites.

  Subsequently, the research group has been able to find people interested in working with them at Fort Benning and Fort Stewart and are currently in the process of pulling together the materials necessary to submit the study for review. This means they must now start the process all over again.

- **Status as of May 29, 1997**

  The investigators can no longer work at the sites proposed originally and are talking to points of contact at Fort Benning and Fort Stewart.

- **Air Force** (sites included Barksdale AFB, Keesler AFB, Howard AFB, and Soto Cano)

  For the Air Force, it was necessary to get approval from the Clinical Investigations group at Headquarters (Bolling AFB). After many discussions with our counterpart at Keesler AFB (who got feedback from their lawyer) and with Lt. Col. Meade Pimsler, Air Force Surgeon General's Office at Bolling AFB, the investigators decided to split the study in two -- Phase 1: Facility Analysis and Ethnographic Research and Phase 2: Large-sample Survey -- and submit phases 1 and 2 separately.

  The Air Force approved phase 1 on **December 18**, and the investigators started working through their counterparts to get approval from the four base commanders. This has been a slow process.

- **Keesler Air Force Base**

  The project counterpart at Keesler AFB, Major Alan Helyer, was reassigned to California in December, and his replacement, Captain Johnson, has been helpful but does not have as much interest in the study as did Major Helyer. The protocol for phase 1 has been moving through the system very slowly.

  **January 30**, Judith McDivitt received a phone call from Major Graziano, the director of the research lab, with some questions about sampling, concerns about some of the questions in the ethnographic study, and concerns about how the data would be used (specifically if data would be separated by service). She sent him a memo addressing these concerns, and the protocol started progressing through channels. Dr. McDivitt has checked in with her new counterpart, Capt. Johnson, several times about progress.

  The latest word, as of **May 6**, was that the legal office at Keesler "had no problem with parts of the protocol, and some problems with other parts. I don't really know what the parts are" [and he couldn't find out]. The legal office had forwarded the protocol up the chain of command and expected it to reach the General within 2 weeks (which would have been last week). Dr. McDivitt has emailed asking for an update, but has not heard anything yet.

- **Barksdale Air Force Base**

  In **December**, the investigators sent their counterpart a copy of the approval memo from Bolling AFB, were told last month that the work could start, and were assigned a point of contact, Captain J.D. Whitlock. The investigators have been working with Captain Whitlock to make arrangements to start the facility analysis and in-depth interviews on Tuesday, June 3.

- **Soto Cano and Howard Air Force Base**

  In **February**, the investigators were informed that the Air Force Commander at Soto Cano had approved the study, but that, because Soto Cano is a joint command, the Army Commander also had to approve the study. The Army component at Soto Cano is under the jurisdiction of Brooke Army Medical Center, which, as noted previously, rejected the study in February and April. One of the BAMC concerns was with the representativeness of our sample of bases. To respond to this concern, in the second application, after discussing the problem with Dr. Modrow and Mr. Laspe, the investigators replaced Soto Cano and Howard with Army and Navy bases located in the U.S.

- **Status as of May 29, 1997**

  The investigators have been approved to work at Barksdale, are waiting for approval at Keesler (there seem to be some problems), and have eliminated Soto Cano and Howard as sites.

- **Navy** (original site was Belle Chasse Naval Air Station):

- **Belle Chasse Naval Air Station**

  Capt. T.A. Hawley, the counterpart at Belle Chasse prepared an IRB application and submitted the entire study (phases 1 and 2) to the Clinical Investigation Department at the National Naval Medical Center in Bethesda in **September 1996**. Please note, this protocol is in a different format and has a different consent form from that submitted to the other bases.

  **September 26**, the Navy approved the study pending several revisions. These revisions were made and sent to Bethesda. Soon after, the investigators heard that parts of the protocol had been lost, so these parts were resent by fax. Last week, the investigators were told that the appropriate person at the IRB did not have a copy of the protocol.

  Today, **May 29**, Krista Brumley, the project coordinator hand delivered the protocol and revisions to Sheila Gaines at the Navy IRB this morning. She was told the investigators should hear back by Wednesday, June 4. The group had hoped to start the facility analysis and in-depth interviews at Belle Chasse during the week of June 9.

- **New Navy Sites**

  In **April**, in response to the BAMC concern about the lack of generalizability of the sites, the investigators started working on getting approval to work at Pensacola Naval Air Station and Mayport Navy Base in Florida. This will provide two larger sites than Belle Chasse and a site with women who are deployed onto ships (Mayport). The investigators have identified two counterparts at Pensacola, Lt. Laura Barton and Ms. Annette Baisden at the Naval Aerospace and Operational Medical Institute, and are preparing to go through the IRB process. The investigators have not yet identified a point of contact at Mayport.

- **Status as of May 29, 1997**

  The investigators are expecting to hear whether they have been approved to start at Belle Chasse on June 4, they are preparing materials for IRB submission at Pensacola,

and they are trying to find a point of contact at Mayport.

- **Army Survey Office Approval**

As required, Judith McDivitt contacted the Survey Office and spoke to Morris Peterson about the process for submitting our instruments. He informed her that, because the study was being carried out across services, that instead of sending the instruments to the Survey Office, she needed to contact the Defense Manpower Data Center. Dr. McDivitt called the DMDC and spoke to Dr. Mary Sue Hay, Chief, Program Evaluation Branch, who told her to send a summary of the protocol and the instruments, which she did on **November 22.**

On **December 12**, Judith McDivitt received a letter from Dr. Hay saying that the facility analysis did not need to be reviewed by her office (although it might need to be licensed) but that the interview guides would need to be reviewed. However, they only review materials at the request of the survey sponsor, not the principle investigator. Thus, she would wait to hear from the project's sponsor.

Dr. McDivitt then sent all the documentation to Catherine Smith at Ft. Detrick, who asked Dr. Hay for more information. Dr. McDivitt thought this matter had been resolved when the Office of Grants and Contracts at Tulane received a letter from Jean Shinbur, contracting officer at Ft. Detrick, dated **January 15** approving the protocol for phase one. However, on **May 29** Judith McDivitt received an email note from Catherine Smith informing her that the Survey Office has to approve the instruments.

- **New Review**

**May 28**, Judith McDivitt received a call from Danny Laspe, Contract Specialist at Ft. Detrick, informing her that, although they had approved the protocol initially, the program officers had now decided to have it re-reviewed by the Surgeon General's Human Subjects Research Review Board (HSRRB) at their meeting on June 11. He asked her to send current copies of the protocol, instruments, and consent forms immediately. She asked him what the group should do about plans to start interviewing at Barksdale AFB next week.

**May 29**, Catherine Smith called to tell Dr. McDivitt that Col. Barts had determined that the investigators should stop working on the studies until after the June 11 meeting. The investigators have postponed the start of interviewing at Barksdale.

**June 11**, Jennifer Strickler and Judith McDivitt attended the meeting of the HSRRB, which was composed of representatives from Ft. Detrick, other military bases in the

Washington area, and representatives from the same committee at BAMC that had rejected the protocol twice before. The investigators' role at this meeting was to answer any questions the reviewers had about the protocol. It was quite obvious from the start of the meeting that the majority of the people on the review board did not like the topic of the study. There were a number of comments and questions about the "current climate" with regard to sex and the military. After the investigators left the room, as they later found out, ten members of the board voted to disapprove the study and two opposed the disapproval, one of the latter making the argument that the HSRRB should not have reviewed this study because it had already been approved by an external scientific review board.

**July 11**, the Office of Grants and Contracts at Tulane received a letter requesting that Tulane and the government negotiate a termination of the cooperative agreement because the research could not be completed without HSRRB approval.

## APPENDIX C -- DEPARTMENT OF THE ARMY LETTER REQUESTING NEGOTIATION TO TERMINATE THE COOPERATIVE AGREEMENT

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH ACQUISITION ACTIVITY
820 CHANDLER STREET
FORT DETRICK, MARYLAND 21702-5014

REPLY TO
ATTENTION OF:

July 11, 1997

Research Contract Branch A

SUBJECT: Cooperative Agreement No. DAMD17-96-2-6026

Ms. Cheryl A. Gros, Director
Grants and Contracts Administration
Tulane University Medical Center
1430 Tulane Avenue

Dear Ms. Gros:

The protocol for use of human research subjects under this cooperative agreement has been disapproved by the Army Surgeon General's Human Subjects Research Review Board (HSRRB). The protocol for this research was initially given administrative approval by the Human Use Review and Regulatory Affairs Division (HURRAD) at The U.S. Army Medical Research and Materiel Command, Fort Detrick. The protocol was then presented to local Institutional Review Boards (IRBs) for approval at potential study sites. When an Army medical center IRB disapproved the protocol for the second time, the protocol was put before the full HSRRB in June 1997. As previously stated, the HSRRB disapproved the protocol.

A copy of the HSRRB minutes regarding the protocol are enclosed. If you desire, a debriefing will be provided. If a debriefing is held, it is requested that Dr. Mc Divitt and one person from the university business office attend. Cooperative Agreement funds may be used to cover travel expenses.

The objectives of the research cannot be attained without approval of the human use protocol. It is proposed that the Government and Tulane University negotiate a mutually agreeable termination of this cooperative agreement. I will be out of the office the week of 14 - 18 July. However, when I return on 21 July, I will contact your office to discuss this matter.

If you have any questions regarding this letter before 21 July, please contact Mr. Brian E. Martin at Area Code (301) 619-7350. After 21 July, please contact me at Area Code (301) 619-7145.

Sincerely,

Danny L. Laspe

Encl

Danny L. Laspe
Contract Specialist

Copies Furnished:

COL Rich, MCMR-PLF
COL Bartz, MCMR-RCQ-HR
Dr. Modrow, MCMR-PLF
Jeannie Shinbur, MCMR-AAA-A

## APPENDIX D -- TULANE UNIVERSITY RESPONSES TO REQUEST TO NEGOTIATE TERMINATION

# Tulane University Medical Center

Office of Grants and Contracts Administration SL82
1430 Tulane Avenue
New Orleans, Louisiana 70112-2699
(504) 588-5613
(504) 584-1748 FAX


September 24, 1997

Danny L. Laspe
Contract Specialist
Department of the Army
U S Army Medical Research Acquisition Activity
820 Chandler Street
Fort Detrick, Maryland 21702-5014

RE: Cooperative Agreement No. DAMD17-96-2-6026

Dear Mr. Laspe:

We feel we have no choice but to agree to the Department of the Army's request to negotiate termination of the above referenced Cooperative Agreement, which was intended to carry out a needs assessment for prevention of pregnancy and sexually transmitted diseases among military women. We are concerned and dismayed by the chain of events leading to this request.

We do not understand how the scientific review committees at BAMC and the HSRRB could re-review, and ultimately disapprove, a research study that already had been approved by an external scientific review committee, the HURRAD, and the Tulane IRB. One of the committee members in the June 11 HSRRB meeting also questioned the HSRRB's authority to reconsider a study that had already undergone scientific review.

The HRSSB's response to this concern was that they, and other institutional review boards, have the responsibility to "look at the scientific quality of protocols where the outcome of poor science may lead to risks...," regardless of whether the protocol has already undergone (and passed) scientific review. This essentially negates the role of the external scientific review committee and leads to some serious questions about the military's commitment to the scientific review process.

The major reason given by the HSRRB for disapproving this study was that "...this protocol, in its current state was not scientifically sound..." As noted previously, the protocol was judged by a scientific peer-review committee to be of sufficient scientific merit and quality to receive funding. Indeed, the approval of HURRAD

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and of several military IRBs (before the change in political climate triggered by the sexual harassment charges at Aberdeen Proving Grounds) indicates that the research design was acceptable to the Department of Defense. In addition, the first phase of the project had been approved, and until we were asked to postpone the activity, was to begin June 2nd at Barksdale AFB.

As detailed in Dr. McDivitt's memo of May 29, during the course of the project, the researchers made every effort to work with the military to develop and conduct a scientifically sound study acknowledging the sensitive context. Initial changes were made in response to comments by reviewers at HURRAD, necessitating an inclusion in the consent forms that is counter to Tulane University policy and that required special approval by the Chancellor. When questions about the methodology have been raised, we have addressed all the concerns, including making major changes to the sample of military bases in the study. The methodological concerns detailed on page 26 of the HSRRB minutes are relatively minor, and could have been easily addressed.

We are sympathetic to the concerns of the Surgeon General's HSRRB committee about the potential unintended consequences of conducting this research in the current political climate. However, as noted in the peer review assessment, the minutes of the Surgeon General's HSRRB committee, and discussions with our counterparts at a variety of military bases, prevention of STDs and of unwanted pregnancy are important and timely topics. We brought together a team of researchers with extensive experience in qualitative and quantitative methods to carry out an innovative study which could have provided valuable information to the military in its continuing attempts to meet the health and related need of its female members.

Termination without cause of the cooperative agreement will result in some damage to Dr. McDivitt's career at Tulane, where funded research is required for tenure. In devoting her time and energy to the cooperative agreement over the past year, she has had to forgo other research and publishing opportunities. From a financial perspective, Dr. McDivitt's 25% effort and salary support budgeted in the second year of the cooperative agreement were factored in when developing Tulane's 97-98 Fiscal Year Budget. We are therefore, requesting that 25% of Dr. McDivitt's salary and fringe for the period 09/23/97 - 06/30/98 ($13,078) be reimbursed, in addition to all year 1 (09/23/96 - 09/22/97) project related expenses ($90,233.05). Please keep in mind that there could be a few outstanding expenses that will be charged to the account, somewhat elevating the year 1 total.

# Tulane University Medical Center

Office of Grants and Contracts Administration SL82
1430 Tulane Avenue
New Orleans, Louisiana 70112-2699
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Please note that we would willingly reconsider conducting this study. All evidence to date indicates an urgent need to address these health threats to women in the military. If you have any questions during this negotiation process, or require additional information, please do not hesitate to contact me.

Sincerely,

Sheryl Gros
Director of Grants
and Contracts Administration

Judith A McDivitt, Ph.D.
Principal Investigator

cc: Ray G. Newman, Ph.D.
John R. Beal, J.D.
Judith LaRosa, Ph.D.
Paul K. Whelton, M.D.

# Tulane University Medical Center

SCHOOL OF PUBLIC HEALTH AND TROPICAL MEDICINE
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Mr. Danny L. Laspe
Contract Specialist
Department of the Army
US Army Medical Research Acquisition Activity, AHN: MCMR-AAA-A
Building 820
Fort Detrick, Maryland 21702-5014

**RE: Judith McDivitt, PhD and Jennifer Strickler, PhD, Cooperative Agreement No. DAMD17-96-2-6026**

Dear Mr. Laspe:

The US Army Medical Research Acquisition Activity has elected to rescind Cooperative Agreement No. DAMD17-96-2-6026 of investigators Drs. Judith McDivitt and Jennifer Strickler. I believe this action is in error and should be reconsidered. Please note that this is not the official letter from Tulane University, but rather a letter from the Chair of Dr. McDivitt's department.

My understanding is that this Cooperative Agreement has been terminated due to some alleged failure on the part of the investigators. Having reviewed the chain of events, that allegation is not at all clear. Indeed, I am struck by the fact that the two investigators have been approved at every step along the process until they came into conflict with some, but not all, of the military review boards. It so happens that the concerns raised were temporally associated with the heightened awareness of sexual harassment within the military and, more specifically, the charges leveled at military drill instructors at the Aberdeen Proving Grounds.

I have no problem with having the Cooperative Agreement rescinded if, in fact, the work is not scientifically valid. Yet, I am puzzled when a study is canceled after a DoD external scientific review committee, the Tulane University Medical Center Institutional Review Board (IRB), HURRAD and several military IRBs found it acceptable. I also find it difficult to accept the rejection when the investigators were initially assured by Ms. Catherine Smith, USAMRMC, that the study could proceed. Furthermore, these two young investigators spent over a year of their valuable career-time working closely with the military personnel at different bases to make the study even more acceptable at different bases – despite the overwhelming initial approval.

In addition, Drs. McDivitt and Strickler expended substantial time and effort working through the labyrinthine military approvals to address the different military groups' requests and obtain approvals. Please note that these requests were often conflictual leaving the investigators confused as to which was the most important request to honor. They also waited weeks for approval to move to the next stage of the implementation process.

The issue of sexually transmitted diseases and unwanted pregnancy among military women is real and of great concern. How do I know this? I am presently a member of the Armed Forces Epidemiological Board (AFEB), which reports directly to the Assistant Secretary of Defense for Health Affairs. I also chair the Subcommittee on Prevention and Health Maintenance of the AFEB. In the course of my service on the board I have been briefed on the status of STDs and unwanted pregnancy among women military personnel across all three services. I can assure you that these conditions represent a substantial threat to military readiness and daily activities. They demand attention. I also note that they pose a substantial risk to male military personnel.

Having been at the National Institutes of Health for many years, most recently as Deputy Director of the Office of Research on Women's Health, I appreciate the need for appropriate handling of sensitive information. However, proactive intervention (in this case intervention for STDs and unwanted pregnancy) seems far more sensible than responding to future allegations of neglect and disregard which could occur if the extent of the problem becomes known. The work proposed by Drs. McDivitt and Stickler would more accurately identify the scope and magnitude of the problem thereby setting the stage for responsible intervention. Such work does not represent a threat to the military, especially if it is conducted as they propose – with tact and utmost confidentiality. Indeed, such work indicates that the military recognizes such issues and is proactively setting about to address them through education and preventive measures – activities which the military carries out superbly! Indeed, I have been impressed, for example, with the important and proactive work the military has done to eradicate drug abuse among personnel.

I urgently request that you reconsider your decision and let these investigators continue their work, with expedited approval. The military, and especially military women, need this information. It is long overdue. I would be pleased to discuss this further and am available at the numbers listed at the top of the letterhead. I can also be contacted through e-mail. Thank you for your consideration.

Sincerely,

Judith H. LaRosa, PhD, RN
Professor and Chair
jlarosa@mailhost.tcs.tulane.edu

CC:
Col Rich, MCMR-PLF
Col Bartz, MCMR-RCQ-HR
Dr. Modrow, MCMR-PLF
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## APPENDIX E-- METHODS SECTION OF PROTOCOL AS OF MAY 13, 1997

The research described here is a pilot study that will use standard epidemiological and social science methodologies. Both qualitative and quantitative data will be collected to assess the needs of servicewomen and evaluate the quality of services at a sample of U.S. military bases. The research consists of three major studies – a facility analysis and an ethnographic study in Phase I, and a large-sample survey in Phase II. This protocol covers Phase I only. Because the research carried out in the first phase will be used to develop the survey instrument for Phase II, the protocol for the survey will be submitted at a later date.

Due to budget limitations, it was necessary to choose a limited number of study sites within easy reach of New Orleans. However, we have attempted to obtain a reasonable cross section of servicewomen by including bases of different sizes with different levels of health care facilities, and bases that include Reserve and CONUS women and women who have been deployed overseas. In consultation with our Army, Air Force, and Navy counterparts, we have identified seven bases and have developed working relationships (or are in the process of doing so) with counterparts at each base.. These sites include:

Fort Benning, Georgia
Fort Stewart, Georgia
Barksdale Air Force Base, Louisiana
Keesler Air Force Base, Mississippi
Belle Chasse Naval Air Station, Louisiana
Mayport Navy Base, Florida
Pensacola Naval Air Station, Florida

Although we have attempted to select a varied sample of bases, findings from this small sample of bases located in the same general geographic area may not be generalizable to military women stationed at different types of bases in different areas of the country. Rather, we see this activity as a pilot study to start examining some important issues related to the health of military women and to contribute to the growing literature in the area. In addition, the findings should be useful to health providers at the seven bases in determining health service and education needs for their female populations.

### A. Facility Analysis

First, an examination of health facilities at the seven sites will be conducted in order to assess the quality and accessibility of contraceptive and STD services available to deployed and deployable women. The facility analysis will consist of (1) an inventory of clinical services, health education programs, and staff available at the health center, and (2) structured interviews with health officers and service providers about reproductive health services and possible barriers to care. The inventory will be conducted with a high ranking health officer in the area of ob/gyn services. This health officer will be selected in cooperation with our counterpart on each base,

and may actually be this counterpart. We will work with our counterpart at each base to identify appropriate respondents among knowledgeable ob/gyn health care providers to be interviewed with the structured interview guide.

(1) Instruments

The instruments for the facility analysis are adapted from the Population Council's Situation Analysis methodology. Situation analysis is an operations research technique for assessment of the functioning of family planning services in developing countries. Six components, or subsystems, are examined: logistics/supplies; physical facilities; staffing; training; supervision; information, education, and communication (IEC); and record keeping. We have adapted the situation analysis inventory and interview instruments for this investigation, focusing only on those aspects of service delivery which are salient to the issue of pregnancy and STD prevention.

(a) Inventory. The facility inventory focuses on the organization and quality of reproductive health care services and facilities, including capacity for pregnancy and STD testing and counseling, health education programs or materials available, staffing, and policies related to reproductive health care and counseling. Health services under deployment conditions are clearly less comprehensive than those available to active duty or reserve servicewomen; hence, much of the effort toward preventing unprotected sexual activity must occur pre-deployment. This inventory will assess the ability of the military to encourage and promote sexual protection among active duty, reserve, and deployed personnel.

(b) Structured interviews. The objective of these interviews with health providers is to identify the "supply-side" barriers to STD and pregnancy prevention, ranging from official policy to medical protocols to personal biases on the part of health care providers.

(2) Confidentiality and Voluntary Participation

The facility analysis interviews will be carried out with health providers that our counterpart at each site has identified as knowledgeable about STD and pregnancy prevention services on the base. We do not expect the respondents to have concerns about the interviews. However, we will take measures to ensure that the interviews are voluntary and confidential. Before the interview starts, each person will be informed that participation is voluntary and that, should they wish to stop the interview or refuse to participate at all, this will remain confidential. The interviews will be conducted by the investigators or a Tulane University graduate student in a private office or room on the base.

We will not record the respondent's name or any other identifying information on the questionnaire to avoid the problem of linking an individual with his or her responses. The data will be analyzed and reported in the aggregate for each facility, not for each individual, thus no

individual will be identified in any presentation of the results. All respondents will be informed that, if they should feel uncomfortable about the interview or any question, they may refuse to answer or stop the interview altogether. A consent form for health providers is included in Appendix B.

(3) Analysis

The facility analysis data are qualitative in nature. Therefore, qualitative analysis methods (described more fully under Ethnographic Research) will be used. We will evaluate the extent to which interviews within a base indicate similar (i.e. uniform) health care delivery. In other words, how much discretion do individual health care providers have in delivering pregnancy and STD prevention services? Unless our results show markedly little homogeneity in within-site health care practices, we will utilize a case study approach to summarize the services at each facility. Secondly, we will merge the facility analysis data with the ethnographic data in order to examine the correspondence between the structure and policies of health care delivery with the attitudes and practices of military women.

## B. Ethnographic Research

In-depth interviews and systematic ethnographic data collection (rapid ethnographic assessment) will be conducted to better understand issues that have not been covered sufficiently in the literature available and that may be unique to military women. These include: attitudes and social norms related to reproductive health behavior and decision-making, knowledge of STDs and health seeking behavior for STDs, attitudes and behavior related to pregnancy, and communication issues. First in-depth interviews will be conducted to explore the experiences of a diverse sample of military women. Following the in-depth interviews, the researchers will develop and conduct a Rapid Ethnographic Assessment (RAP) for STD and pregnancy- related issues. The results from the rapid ethnographic assessment will be used to develop the survey component in Phase II.

(1) In-depth Semi-Structured Interviews

This section of the study is a form of pilot or formative research designed, not to provide final or definitive evidence, but rather to explore a range of issues related to the research topic at hand. These findings then can be incorporated into final research instruments such as the RAP guides and the survey.

(a) Sample size and recruitment

Approximately five in-depth interviews will be conducted with key informants on each of the 7 bases, thereby including women from the three branches of the military. The women will be recruited through a purposive or judgment sampling process. This sampling method is used frequently in exploratory and ethnographic studies for the

selection of key informants (people who are knowledgeable about the issues to be discussed and who can represent their peers). Random selection of individuals from a population rarely produces a sample of good key informants. First, the qualities that make a good key informant are not uniformly distributed in a population. Respondents need to be knowledgeable and able to express that knowledge articulately. Often this requires respondents who have distanced themselves somewhat from the events they are describing. Second, we are inquiring about system-level, not individual-level variables in this part of the study. Knowledgeable and intelligent respondents should be able to describe general conditions for the base and the experience of others, independent of their own experiences. The sampling method is described in more detail below.

Our counterpart at each base will identify a list of approximately 25 women that could potentially be good key informants. We will ask him or her to include enlisted personnel and officers, and a mix of women from the different units on the base to ensure that we do not get a list only of women working at the medical center. In addition, we will request that the list include women of various ages, marital status and ethnic backgrounds in an effort to have a diverse sample population with whom we can speak.

We will then contact the women on this list until we have identified five respondents who would be appropriate for participation in the in-depth interviews and who are willing to speak to us. If five women who meet the recruitment criteria of knowledge and articulation cannot be found among this initial list, we will ask the women in the sample to identify five friends or acquaintances with whom we can speak. We will randomly select one out of the five people named and continue the procedure until appropriate respondents are identified.

It is essential to note that the selection criteria do not involve identifying a particular piece of knowledge, such as a women's positive or negative feelings about the services provided. Rather they reflect knowledge of the services provided and an ability to discuss their pros and cons. Therefore, it is not necessary for selection to be completely random. As discussed above, however, we are taking the necessary precautions towards selecting a sample that is as representative of the population as possible.

(b) Confidentiality and voluntary participation

Participation in this research is voluntary. Any women who refuses to participate in the in-depth interview will not be identified to anyone. All women will be informed at the beginning of the interview that their participation is voluntary and that they may refuse to answer any questions, refuse to have the session taped or request that the tape recorder be stopped at any point, or discontinue the interview at any time.

We do not anticipate any major problems with discomfort or confidentiality. The issues discussed, however, are sensitive. Therefore, the women will not be asked to talk about their own behavior, but rather to talk about general behavior and reproductive

health concerns of women in the military. The interviewer will have on hand a list of contacts if the respondent should want to discuss the interview with anyone, including a health provider.

To ensure confidentiality, no names will be identified on either the field notes or the tapes. The field notes will be linked with each tape by a coded number. At the completion of the study, the tapes will be destroyed.

(c) Interviewer recruitment and training

In-depth and rapid assessment interviewers will be recruited from among the female graduates students at the Tulane School of Public Health and Tropical Medicine. Only those who have taken courses in qualitative research will be considered, and preference will be given to those with qualitative interviewing experience.

The interviewers will go through a three-day training session conducted by the research staff. This will include classroom and field training in methods for the in-depth interviews and the rapid ethnographic assessment. After the rapid assessment guide has been developed, the interviewers will be given a one-day refresher session to give them familiarity with the completed guide.

(d) Instrument

Using ethnographic interviewing methods for this study will allow a greater richness in the data. In-depth interviews are generally extended discussions about the topics of research with probing. This will allow the women to freely express specific "stories" that are relevant to the research topic. This type of freedom is typically not feasible in a more structured interview or survey setting.

The data for this study will be collected using a semi-structured interview guide consisting of a list of topics of interest. The interviewers will use the guide as a framework to ensure that all topics are covered, but will also carefully monitor what the respondent is saying for new or unexpected information, and will probe for more information as necessary. Some probe guidelines or points will be written on the guide next to various topics. Probing may also include the use of expressions such as "like where" or "then what happens," as well as silent pauses. The interviews may take two hours or longer, although we estimate they should take approximately one hour. However, this is under the control of the respondent, who can end the interview at any time.

The interviews will be reviewed each night by the field supervisor, who will report back to the researchers in New Orleans. If important topics have not been covered in sufficient depth, additional interviews may be required. A report on the in-depth interview activity will be prepared after its completion. Information gathered in the in-depth interviews will then be used to develop the rapid assessment guides.

(e) Analysis

Notes will be taken during the in-depth interviews. These field notes will then be expanded, documented and entered into a computer using software developed for the indexing and analysis of qualitative data (e.g., Nu*dist). Although the interviews will be tape recorded, the tapes will not be transcribed. Instead, they will be used to assist in writing up the field notes and also for extracting quotations. Choosing salient quotations is crucial in presenting qualitative data. Often a single sentence or two can bring it all together and illustrate a particularly noteworthy point. The field notes and tapes will be stored in a locked file cabinet at Tulane and will be destroyed at the completion of the study.

Analysis will consist first of all the researchers and interviewers reading through the field notes and developing a preliminary indexing scheme. We will look for information related to the topics on the interview guide, but will also be open to allowing patterns and unexpected information to emerge from the data. The computer program will then be used to index and classify the data in a more formal way that can be printed out and used in developing the rapid assessment guide and a report of the findings.

(2) Rapid Ethnographic Assessment (RAP)

(a) Site location, sample size and recruitment

As with the in-depth interviews, the rapid ethnographic assessment study take place at all seven sites. The sample population will include active duty and Reserve women, along with women who have been deployed overseas and who can discuss their experience retrospectively.

The sample will be selected through a snowball sampling process with some random selection of respondents. Each interviewer will follow the process below in selecting women for interviewing.

1. Key informants interviewed in the in-depth study will be asked to name five varied friends or acquaintances with whom we may talk.
2. A single contact from this list will be selected at random and will be contacted for an interview. After the interview, the respondent will be asked to name five friends and acquaintances who might be able to provide a good picture of the topics covered.
3. This will proceed until all interviews are completed.

If a potential respondent does not wish to participate in the interview, we will still ask for a list of contacts who might be interested. If she does not wish to provide such a list, her name will be struck from the list of contacts and another selected at random.

(b) Confidentiality and voluntary participation

As with the in-depth interviews, the rapid ethnographic research is also voluntary. Women who refuse to participate will not be identified to anyone as having refused. All women will be told at the beginning of the interview that their participation is voluntary and that they may refuse to answer any questions or stop the interview at any time. The respondents may also request that the tape recorder be turned off at any time during the interview.

We do not expect problems with discomfort or confidentiality in the ethnographic studies. The women will not be asked to talk about their own behavior, but to talk about general behavior and concerns in the military. Interviews will take place at a location on the base that women see as private and non-threatening (still to be determined for each site). At the end of each day of interviewing the completed notes and tapes will be given a code number to help identify which notes go with which tape, but this code will not be linked to the respondent's name. The tapes will be destroyed as soon as the interviews are transcribed. Documentation will be kept in a locked file cabinet in the project office at Tulane University. Access to this office and file cabinet will be given only to members on the research team. Similarly, any work conducted on the computer will also have limited accessibility.

(c) Instruments

The rapid assessment guides will address in more detail issues identified in the earlier research as those most important to understanding STD and pregnancy prevention among military women. We expect to ask about different beliefs, attitudes, behavior, and norms.

The guides will incorporate in-depth questions, closed-ended questions, and free-listing and case frame items depending on which is the best format for collecting the information needed. Because the RAP guides will be based on the findings from the in-depth interviews, we cannot predict with certainty what items will be included.

Free-listing is a technique embedded in the structured guides, and is used in ethnographic research to define domains or to generate terms within given categories. Respondents are asked to name all items in a certain category, such as concerns about women in the military. Items from each are tabulated according to two indicators of salience: frequency mentioned and position on list. Once the respondent has listed items, the investigator will ask her to explain the responses and to differentiate items from each

other. This probing will assist later in the interpretation of classifications. All 30 respondents at each site will be asked to participate in free-listing, a large enough number to ensure high levels of validity.

(d) Data collection

As noted previously, graduate students with previous qualitative interviewing experience will be hired to carry out both the in-depth interviews and the rapid ethnographic assessments. A refresher training session will be given on use of the RAP instrument and the sampling procedure for the RAP before these interviews start. Interviewers will go to a base as a team, with a field supervisor (K. Brumley, the project coordinator). At the end of each day of interviewing, the team will review their field notes and report back to the researchers in New Orleans. This process will allow us to ensure that we are obtaining a reasonably diverse sample through our sampling process (or make adjustments) and to judge the quality and completeness of the data.

(e) Coding and Analysis

Before formal analysis of the ethnographic data, we will carry out the following activities: computer data entry, coding, reliability checks, and descriptive analyses for subject characteristics. The rapid assessment interviews will be documented in field notes and on tape and will be entered into a microcomputer using available word processing software (Word for Windows). Actual transcripts will be coded independently for comparison and reliability. As with the data from the in-depth interviews, the transcripts and notes will be indexed and analyzed using free-form text indexing and retrieval software (e.g. Nu*dist or After for Windows).

An essential step in preparing the RAP data for analysis will be to ensure intercoder reliability among those who are coding the data for analysis. The following activities will be carried out: training of interviewers to recognize the boundaries for each issue or topic, and providing periodic consensual retraining as new issues emerge from the data; individual indexing of the data, to ensure the maximum exploration of emergent theory and conditions; and consensual confirmation or resolution of the final designation of all text segments and their coding to eliminate idiosyncratic errors in analysis.

The interview data will be analyzed with a multi-level coding scheme which addresses content and process areas of interest. The use of computer based textual management programs will allow flexible handling of content areas which are embedded in the text itself. Development of the coding scheme for field notes and verbatim transcripts in this study will be carried out collectively by the investigators, in consultation with other team members. The basic computer data management program to be used is Nu*dist, a text analysis package which permits different aspects of exploratory and confirmatory textual analysis. It allows the researcher to categorize text by building a tree with different issues or topics as branches. The researcher then can place relevant text in the appropriate

section of the tree and then easily review the data under the various topics.

Free list data from the rapid assessment guides will be entered into a computer software package called ANTHROPAC. A list will be generated with all the items mentioned, the frequency each item was mentioned and the percentage of respondents mentioning each item. This program will then perform hierarchical clustering and multidimensional scaling to construct a taxonomy of relationship types and to determine similarities and differences.

(f) Limitations

Due to the exploratory nature of this study, the results will not be generalizable to the military as a whole, to all women in the military, or even to all women on a particular base. However, they will give us a better picture of life in the military on the bases included in the study and will provide valuable information for use in finalizing the rapid assessment guides and in developing the survey. Moreover, the information gathered will assist in other studies on this topic and guide the military in making changes to the health structure as needed.

## C. Structured Interviews

The results of the qualitative phase of the study will be used to generate a structured interview schedule which will be administered to a sample of approximately 1200 military women during the second year of the study. The results of these interviews will provide more objective and quantifiable information on the incidence and determinants of STDs and unintended pregnancy among women in the military.

## D. Summary of Data Bases to be Used

The three research components will result in five databases, all of which will be used in the final analyses.

(1) The facility analysis will produce two data sets. The first, an inventory of pregnancy and STD services and supplies available at each site's health facility, including days of service; staffing; IEC materials, counseling services, and contraceptives available; record keeping; and management and supervision of staff. The second data set will come from interviews with several providers in each health facility and will be in the form of a text file of primarily open-ended responses to provide more detail on services offered, how activities are carried out, and suggestions for improvements to the system.

(2) The ethnographic research will result in two qualitative data bases in the form of text files. The in-depth interview database will report women's extended responses to open-ended questions

about their life in the military, sexual norms and decision making, STDs and STD health-seeking decision making, and pregnancy issues. The rapid assessments also will produce a data base consisting of lists of words identified by the respondents when asked to "freelist" words in a certain category, along with longer explanations for their choices.

(3) The structured interviews will produce a data base of quantitative survey results in a format that can be analyzed using the major statistical packages available (SPSS, SAS, EPINFO). This data base will include responses from approximately 1200 women to questions about their demographic characteristics, pregnancy and STD occurrence, sexual behavior, alcohol use, and knowledge and attitudinal factors identified in the qualitative research.